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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,416	11/28/2000	Hong Jin	7682-052-999	7604

20583 7590 07/10/2006

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

1. Currently, claims 49, 51-53, 55-58, 60-63, and 65-83 are pending and under consideration in the application.
2. In the prior action on the merits, mailed on February 7, 2006, claims 49, and 51-53, 55-58, 60-63, and 65-83 were pending and rejected. In the Response filed on May 8, 2006, claims 49, 57, 58, 70, 73, 74, and 76 were amended; and claims 55, 60, 65, 75, and 79 were cancelled.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on May 8, 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 101

4. **(Prior Rejection- Withdrawn)** Claims 49, 51-53, 55-57, 60-63, 69, 71-73, 75, 77, 78, 83 were rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Applicant's argument that the requirement that the claimed compositions comprise "recombinant" RSV viruses excludes naturally occurring viruses is found persuasive. The rejection is therefore withdrawn.

Claim Rejections - 35 USC § 112

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5. **(Prior Rejection- Withdrawn)** Claim 76 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim purports to depend from claim 732. In view of the amendment of the claim, the rejection is withdrawn.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. **(Prior Rejection- Maintained)** Claims 49-53, 55, 56, 70, 71, and 73-83 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain recombinant attenuated RSV viruses as vaccines, does not reasonably provide enabling support for the use of any of the claimed viruses as anti-RSV vaccines. Claims 50, 55, 75, and 79 have been cancelled. The remaining claims have been amended to read on embodiments wherein the genetic modification is a deletion.

The Applicant traverses the rejection on the basis that the application is enabling for the claimed vaccines. The applicant asserts that, as described in the Spaete Declaration, the teachings of the application enable those in the art to make and to use recombinant attenuated non-segmented RNA viruses as vaccines. While it is accepted that the teachings of the application enable those in the art to make recombinant RSV viruses comprising modifications, the Examiner does not agree that the teachings of the present application enable those skilled in the art to make and use any such virus as a vaccine. As was indicated in the prior actions, there is significant uncertainty in the art as to the effects of any particular modification to the viral

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genome, and as to what modification or combination of modifications would ultimately result in an effective vaccine virus.

Thus, while the Applicant's arguments have been considered, they are not found persuasive in demonstrating that the Applicant has enabled the use of any of the claimed viruses as a virus, and particularly for use as an anti-RSV virus. While the application does provide relevant teachings, these teachings are not sufficient to overcome the significant and multiple grounds of unpredictability in the art, particularly in view of the breadth of the claims which exceeds the scope of any specific examples provided in the application. It is noted that the rejection is not on the basis that the Applicant is not enabled for any vaccine, but that the Applicant is not enabled for the use of the full scope of modified viruses being claimed.

The teachings of the Declaration establish that those in the art may be able to make useful attenuated vaccine viruses. However, the declaration does not establish that the teachings of the application would have provided adequate guidance for those of ordinary skill in the art to make and use any virus falling within the scope of the claims. Further, it is additionally noted that the present application provides no examples of modified attenuated viruses comprising a deletion of other than a complete open reading frame. The rejection is therefore maintained.

8. **(Prior Rejection- Maintained)** Claims 49 and 51-83 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims read on genetically manipulated (recombinant) attenuated infectious RSV comprising any insertion or deletion, or any insertion, substitution, or deletion of an entire open reading frame (ORF). Claims

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49, 51-53, 56-58, 61-63, 66-74, 76-78, and 80-83 remain pending, and have been amended to read on compositions wherein the modified viral genome may comprise any deletion.

The Applicant traverses the rejection further arguing the analogy between the present case and the situation in the *Wands* case. While the Applicant describes similarities between the two situations, the Applicant does not show one factor that was deemed important to the *Wands* decision. As was noted in the prior action, the *Wands* method was carried out several times, and each time an antibody meeting all of the claim limitations was produced. There is no such demonstration in the present case. In addition, the art of making antibodies is generally well understood. However, as has been previously described above and in the prior actions, the art of making modified viruses comprises several grounds for uncertainty. Thus, because the present application has not demonstrated that use of any disclosed method would routinely produce a virus as claimed, in view of the breadth of the claims (reading on any attenuated non-segmented RNA virus comprising any deletion), and in view of the unpredictability in the art, the Applicant's arguments are not found persuasive and the rejection is maintained for the reasons above and the reasons of record.

9. **(Prior Rejection- Maintained)** Claims 49, 51-53, 55-58, 60-63, 65-83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims were rejected as lacking sufficient written description support for the claimed general of viruses comprising any recombinant RSV comprising any insertion, deletion, or addition resulting in an attenuated virus, or in a subset of such attenuated viruses that are either capable of inducing a protective or therapeutic immunogenic anti-RSV response, or capable of only a single

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round of replication. Claims 55, 60, 65, 75, and 79 have been cancelled. The rejection is therefore withdrawn from these claims. The remaining claims have been amended to require that the modification to the viral genome is a deletion.

The Applicant asserts that the present case is analogous to the situation in *Invitrogen v. Clontech*, 77 U.S.P.Q.2d 1161, in that the present application has identified a structure that correlates to the required functions of the claimed inventions. This assertion is not found persuasive for the reasons in the prior action. In the *Invitrogen* case, the patentee claimed a modified enzyme having one activity and lacking another. The court found descriptive support in that several species of the genus had been provided, and in that the art had a clear correlation between the function and a given structure of the relevant gene. In the present case, the Applicant asserts that there is a known function between the structure and function of individual genes in the claimed viruses.

This argument is not found persuasive because, while the functions of the wild-type viral proteins may be understood to various extents, the claims are not directed to the proteins but to recombinant viruses with particular functional characteristics. The application does demonstrate any correlation between any non-segmented RNA viral genome comprising any deletion with any of the indicated functional characteristics. Rather, as was pointed out in the prior action, different modifications to different positions in the same region, and in different regions, of the viral genomes results in products with different functional characteristics. The rejection is therefore maintained for the reasons above, and for the reasons of record.

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10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **(Prior Rejection- Maintained)** Claim 72 was rejected under 35 U.S.C. 103(a) as being obvious over Murphy et al., U.S. Patent 5,993,824 (of record in the action mailed on June 5, 2002). The Applicant traverses this rejection on the basis of the claim to priority to earlier application 08/316439, now U.S. patent 5,80,520. The Applicant's arguments have been considered but are not found persuasive. There is no support in the priority document for embodiments of the recombinant RSV comprising the specific deletion of the M2-2 ORF. The rejection is therefore maintained.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. **(Prior Rejection- Maintained)** Claims 49, 51-53, 55-58, 60-63, 65-83 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7, 10, 12, 21, and 22 of copending Application No. 09/724,388. As no arguments in traversal of this rejection have been provided, the rejection is maintained against pending claims 49, 51-53, 56-58, 61-63, 66-74, 76-78, and 80-83. .

14. **(Prior Rejection- Withdrawn)** Claims 49, 51-53, 55-58, 60-63, 65-83 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-31, 34, and 36 of copending Application No. 10/876,113. Because claims 26-31, 34, and 36 have been withdrawn from consideration in the copending application, the rejection is withdrawn.

15. **(Prior Rejection- Maintained)** Claims 49, 52, 55-58, 60, 61, 63, 65, 66, 68, 70, 72, 73-76, 78-80, and 82 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 2, 17, 18, 23, and 35 of copending Application No. 10/975,060. In view of the cancellation of claims 55, 60, 65, 75, 79, the rejection is withdrawn from these claims. It is noted that claims 2, 17, 18, 23, and 35 of the copending application have been cancelled. However, new claims 36, 37, 39, and 41-43 still represent species of the present claims. As no argument in traversal of the rejection has been presented, the rejection is maintained.

16. **(Prior Rejection- Maintained)** Claims 49, 52, 55-58, 60, 61, 63, 65, 66, 68, 70, 72, 73-76, 78-80, and 82 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/078,900. This rejection is maintained with respect to pending claims 49, 52, 56-58, 61, 63, 66, 68, 70, 72, 73, 74, 76, 77, 78, 80, and 82; and is withdrawn from the other claims which have been cancelled from the application.

17. **(Prior Rejection- Withdrawn)** Claims 49, 52, 55, 57, 58, 60, 63, 65, 68, 71, 73-75, 78, 79, and 82 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6 and 7 of U.S. Patent No. 5,840,520. In view of the amendments of the present claims, the rejection is withdrawn.

Conclusion

18. No claims are allowed.

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

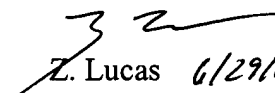
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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas 6/29/06
Patent Examiner



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